DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service D1166B

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

FEB 5 1997

VIA FEDERAL EXPRESS

Steven Gex
President and Chief Executive Officer
Biopsys Medical, Incorporated
3 Morgan
Irvine, California 92618

Dear Mr. Gex:

As part of the Food and Drug Administration's (FDA's) surveillance of promotion and advertising of devices regulated by the Center for Devices and Radiological Health (CDRH), we have recently read a number of news articles and press releases, available on the Nexis database, that discuss the Biopsys Medical Inc. (Biopsys) biopsy device (the BMI device), which is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The device, as cleared under several 510(k) premarket notification submissions, has been identified by the company as the BMI device. Biopsys has also marketed this device as the Mammotome Biopsy System. One of the items we reviewed is a Business Wire press release issued by Biopsys on December 2, 1996. The heading of the release is "New ultrasound design expands Mammotome applications," and the release makes numerous statements referring to the "Mammotome Biopsy System." Another is an Investor's Business Daily press release issued on December 16, 1996, entitled, "Biopsys Medical Inc." A third is a Business Wire press release issued by Biopsys on January 15, 1997.

clearance of the company's 510(k) notification for the BMI device, k953399, was for "use for soft tissue removal for a biopsy, definitive diagnosis or confirmation of a clinical diagnosis."

not expressly or impliedly promote the device for excision of breast cancer or generate advertising or promotional labeling making claims about excision.

However, the company's press release noted above makes numerous inappropriate statements

that, as explained below, both expressly and impliedly promote your device for uses for which it was not cleared, and that have misbranded and adulterated the device.

While not referring specifically to cancerous lesions, the claims made in the press release imply the excision of a lesion rather than the removal of a sufficient amount of tissue for diagnostic purposes. Although Biopsys has not made any claims or statements that use of the biopsy system on small lesions will not require additional follow-up procedures, your release clearly sends the message that use of your devices is effective in removing entire lesions, especially small ones.

For example, the release refers to the recently introduced 11-gauge Mammotome probe and MicroMark Clip as enabling physicians to take larger breast tissue samples and mark the biopsy site for follow-up examinations. In that context, it quotes radiologist Anne Smid as saying, "Small lesions are one of the areas where the Mammotome for ultrasound will be widely used. There is no reason to leave part of the sonographic evidence of the lesion if you can insert the MicroMark Clip to mark the area. The 11-gauge probe is large enough that if you have a small nodule or mass a thorough biopsy is possible." The release continues, "This makes future follow-up of the patient much less problematic because the sonographic evidence of the lesion is no longer present on imaging studies to potentially confuse other physicians. The probe can more completely biopsy an abnormality because it obtains eight times more tissue per acquisition than core-needle biopsy." This discussion implies that the placement of a radiographic clip is necessary because of the complete removal of at least small lesions. This impression is compounded by the statement attributed to Dr. Steven Parker, referring to patients watching the ultrasound-guided biopsy, ". . .When they see the lesion literally disappear before their eyes, their confidence in the procedure skyrockets." A lesion disappearing before one's eyes is a lesion that has been excised.

We have an additional concern. The device was not cleared with a claim for use as a breast biopsy device.

The device was cleared for marketing as a gastroenterology-urology biopsy instrument, the intended use for which is provided in FDA's regulations at 21 CFR 876.1075. That section provides that a gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classifications regulations in other parts of the device classification regulations. Your company's use of the name "Mammotome" or "Mammotome Breast Biopsy System" implies specific use as a breast biopsy device. The company's press releases, like other Biopsys promotional materials that we have reviewed, also make explicit claims for the device as a breast biopsy device. Such claims should only be made for a device cleared for that intended use.

Promoting the BMI device for breast biopsy and for the excision of lesions has, therefore, misbranded your device under section 502(o) of the act in that appropriate premarket notification required by section 510(k) of the act was not submitted. The FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Naming the device with a word that clearly implies use in the breast and making claims for breast biopsy and for excision of tissue impermissibly change the intended use of the device. Pursuant to section 510(k) of the act and as explained in 21 CFR 807.81 (a)(3)(ii), such changes require the submission of premarket notification.

In addition, the BMI device marketed with claims for breast biopsy and for excision of tissue is adulterated within the meaning of section 501(f)(1)(B) of the act in that it is a class III device under section 513(f) of the act, and does not have an approved application for premarket approval in effect pursuant to section 515(a) of the act, or an approved application for an investigational device exemption under section 520(g).

In the Investor's Daily press release, you are quoted as saying that a woman can drive herself home right after the procedure with just a Band-Aid on her breast and that you "don't think it's even as bad as getting a crown." If this quote is correctly attributed, then you have made a claim that requires substantiation. The Biopsys January 15 press release says "Biopsys Medical Inc. is a leading developer, manufacturer and marketer of products for the diagnosis and management of breast cancer. Through its principal product, the Mammotome Biopsy System, the company offers a less-invasive, cost-effective alternative to open surgical biopsy."

not make cost effectiveness claims until data supporting the claims had been submitted to FDA. To date, such data have not been submitted to the agency.

This letter is not intended to be an all-inclusive list of deficiencies associated with the Biopsys biopsy system. It is your responsibility to ensure adherence to each requirement of the act and the Federal regulations. The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of the receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address false and misleading information currently in the marketplace and actions to

prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA240), 19900 Mac Arthur Blvd., Suite 300, Irvine, California, 92612-2445.

Sincerely yours,

Byron Tart for

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health